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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,873	01/21/2004	Nicholas M. Valiante	PP20203.003	5927

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,873	VALIANTE, NICHOLAS M.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-11,18 and 20-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-17, 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/25/2006 has been entered.

Claim(s) 1-31 are pending. Claim(s) 1-11, 18, 20-31 have been withdrawn. Claim(s) 12-17, 19 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and repeated below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-17, 19 are rejected under 35 U.S.C. 103(a) as being obvious over Baker et al. (US Patent 5,441,955).

The instant claims are directed to a composition comprising a tryptanthrin compound (No. 1001) and an antigen.

Baker et al. teach the tryptanthrin compound of No. 1001 in the applicant's specification (col. 20, lines 22-33) as part of an antimicrobial composition (abstract). Furthermore, this tryptanthrin compound can be administered with an adjuvant (col. 12, lines 37-42). What's more, Baker et al. teach that tryptanthrin can be administered in combination with one or more other agents used in the treatment of pathogenic mycobacterial infections. Representative agents used for the treatment of mycobacterial tuberculosis include, for example, isoniazid, rifampin, pyrazinamide, ethambutol, rifabutin, streptomycin, and ciproflaxin (col. 13, lines 35-43). Examiner would like to point out that mycobacterial tuberculosis is a common cause of bacterial meningitis (meningococcus infection). Moreover, Bacillus of Calmette and Guérin (BCG) is a vaccine against tuberculosis caused by mycobacterial tuberculosis.

Baker et al., however fails to disclose a specific combination of the tryptanthrin compound (No. 1001) and an adjuvant.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine the tryptanthrin compound (No. 1001) with an adjuvant.

A person of ordinary skill in the art would have been motivated to make this combination because of the increased antigenic response of the tryptanthrin compound resulting from the adjuvant, which is defined as the agents that are used for the treatment of mycobacterial tuberculosis.

Response to Arguments

Applicant argues that there is no motivation in the cited reference to combine BCG with tryptanthrin. Specifically, Applicant argues that Baker neither discloses BCG as an adjuvant nor an antimicrobial agent that would be combinable with tryptanthrin.

Examiner respectfully argues that there is ample motivation to combine BCG with tryptanthrin as disclosed in Baker et al. Tryptanthrin can be administered with an adjuvant, such as an agent used in the treatment of pathogenic mycobacterial infections. Representative agents used for the treatment of mycobacterial tuberculosis include, for example, isoniazid, rifampin, pyrazinamide, ethambutol, rifabutin, streptomycin, and ciproflaxin (col. 13, lines 35-43). Examiner would like to point out that mycobacterial tuberculosis is a common cause of bacterial meningitis (meningococcus infection). Moreover, Bacillus of Calmette and Guérin (BCG) is a vaccine against tuberculosis caused by mycobacterial tuberculosis. Whether this is cited in the

background or not is irrelevant, since BCG is clearly disclosed to treat mycobacterial tuberculosis.

Applicant argues that BCG is not an adjuvant.

For the sake of argument, even if BCG does not qualify as an adjuvant, it still would be obvious to one of ordinary skill in the art to combine BCG with tryptanthrin because they are used for the same purpose.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

In response to the limitation imposed on claim 15 by amendment, the enhancement of the immune response to the antigen by the tryptanthrin compound is inherent since a compound and its properties are inseparable.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Applicant also argues that there is no motivation to combine BCG with tryptanthrin because BCG is a vaccine made up of a live strain of Mycobacterium, which require multiplication and growth in the recipient. This is in direct contradiction to tryptanthrin compounds, which inhibit the growth of pathogenic mycobacteria, therefore diminishing or eliminating BCG's ability to produce immunity against Mycobacteria infections.

This is not persuasive because it is well known to one of ordinary skill in the art that BCG is a non-specific immunostimulatory agent. This will give a general boost of the immune system in the host. BCG is well known to be administered with a variety of therapeutic agents for a variety of disorders and diseases. Further, there is no certainty that tryptanthrin will inhibit the actual specie, Mycobacterium tuberculosis, even though the general teaching that tryptanthrin inhibits the growth of pathogenic mycobacteria.

Examiner also notes that Applicant is essentially arguing against the instant invention. If Applicant continues with this line of thought, then the Examiner respectfully requests more clarification as to how the instant invention pertaining to a composition comprising tryptanthrin and BCG is enabled.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the

grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

S. Wang

SHENGJUN WANG
PRIMARY EXAMINER